

**ENLYTE- leucovorin, folic acid, levomefolate magnesium, ferrous cysteine glycinate, 1,2-docosahexanoyl-sn-glycero-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycero-3-phosphoserine calcium, phosphatidyl serine, pyridoxal 5-phosphate, flavin adenine dinucleotide, nadh, cobamamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium l-threonate and betaine capsule, delayed release pellets**  
**Jaymac Pharmaceuticals LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**EnLyte® with DeltaFolate™**

EnLyte®

with DeltaFolate™

**[2.5 mg F-THf, 1mg PteGlu, 7mg Me-THf][50 mcg CBI][1.5 mg FeGC]**

**JAYMAC Pharmaceuticals, LLC**

Softgels (30ct bottle)

Prescription **Vitamin** *For Therapeutic Use*

**Description**

**EnLyte®** is an orally administered prescription **vitamin** for *therapeutic use* formulated for adult patients - ages 12 and up, who are under specific direction and monitoring of homocysteine (HCY) status by a physician. A recent study<sup>+</sup> suggested that **EnLyte®** was effective in lowering homocystine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).

<sup>+</sup> *ClinicalTrials.gov identifier: NCT02709668, Correlation of Clinical Response With Homocysteine Reduction During Therapy With Reduced B Vitamins in Patients with MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism.*

**OTHER INGREDIENTS:** 25 mg ascorbates<sup>4</sup> (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate), 500 mcg betaine (trimethylglycine), 13.6 mg FeGC<sup>3</sup> (1.5 mg elemental iron from ferrous glycine cysteinate), 25 mcg flavin adenine dinucleotide (reduced vitamin B<sub>2</sub>), 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride (reduced vitamin B<sub>3</sub>), at least 19.2 mg phospholipid-omega complex<sup>5</sup>, 25 mcg pyridoxal 5' phosphate (reduced vitamin B<sub>6</sub>), 25 mcg thiamine pyrophosphate (reduced vitamin B<sub>1</sub>).

**EXCIPIENTS:** Amatto [colorant], at least 5.5 mg citrates (*at least 1.83 mg citric acid, at least 3.67 mg sodium citrates*), gelatin (bovine), glycerine, piperine, plant lipids (sunflower), purified water, ubidecarenone, yellow beeswax.

<sup>1</sup> *Coenzyme B<sub>12</sub> is the primary form most found in mammalian liver*

<sup>2</sup> *Derived from folinic acid - a provitamin of B<sub>12</sub> cofactor, l-methylfolate*

<sup>3</sup> *Pure amino acid, cysteinated iron chelate as AminoFer™ under exclusive license*

<sup>4</sup> *30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics*

<sup>5</sup> *Contains at least 12 mg phosphatidylserine (PS)– of which approximately 6.4 mg as PS-DHA-Ca, and less than 1% EPA (<800 mcg PS-EPA-Ca)*

**CONTAINS FISH/KRILL/SOY.** No artificial colorants. No dairy, wheat, sugar or egg.

**INDICATIONS:**

**EnLyte®** is indicated in the TREATMENT of vitamin deficiency - specifically vitamin B<sub>12</sub> deficiency,

and the PREVENTION of vitamin B<sub>12</sub>-cofactor deficiency, l-methylfolate.

## MECHANISM OF ACTION:

VITAMIN B<sub>12</sub> [TREATMENT]; FOLATE [PREVENTION]

### WARNINGS:

1. **Caution: This product is not suitable for the TREATMENT of vitamin B<sub>12</sub> deficiency secondary to either pernicious anemia and/or gastrointestinal malabsorption (i.e., exocrine pancreatic insufficiency).**
2. *Caution: The use of vitamin B<sub>12</sub> for the TREATMENT of anemnia without direct supervision of a physician may be dangerous.*

**Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962. KEEP THIS OUT OF THE REACH OF CHILDREN.**

## ADVERSE REACTIONS:

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of vitamin B<sub>12</sub>. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B<sub>9</sub>.

## PRECAUTIONS:

0.1 mg or more of vitamin B<sub>9</sub> daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B<sub>9</sub> in treating vitamin B<sub>12</sub>-deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B<sub>12</sub> deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when vitamin B<sub>9</sub> therapy is used as the only hematopoietic agent. Doses of vitamin B<sub>12</sub> exceeding 10 mcg daily may produce hematologic response in patients with vitamin B<sub>9</sub> deficiency. Indiscriminate administration may mask the true diagnosis. *A dietary deficiency of only vitamin B<sub>12</sub> is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.*

## DOSAGE AND ADMINISTRATION:

The adult dose is one capsule daily *preferably* on an empty stomach.

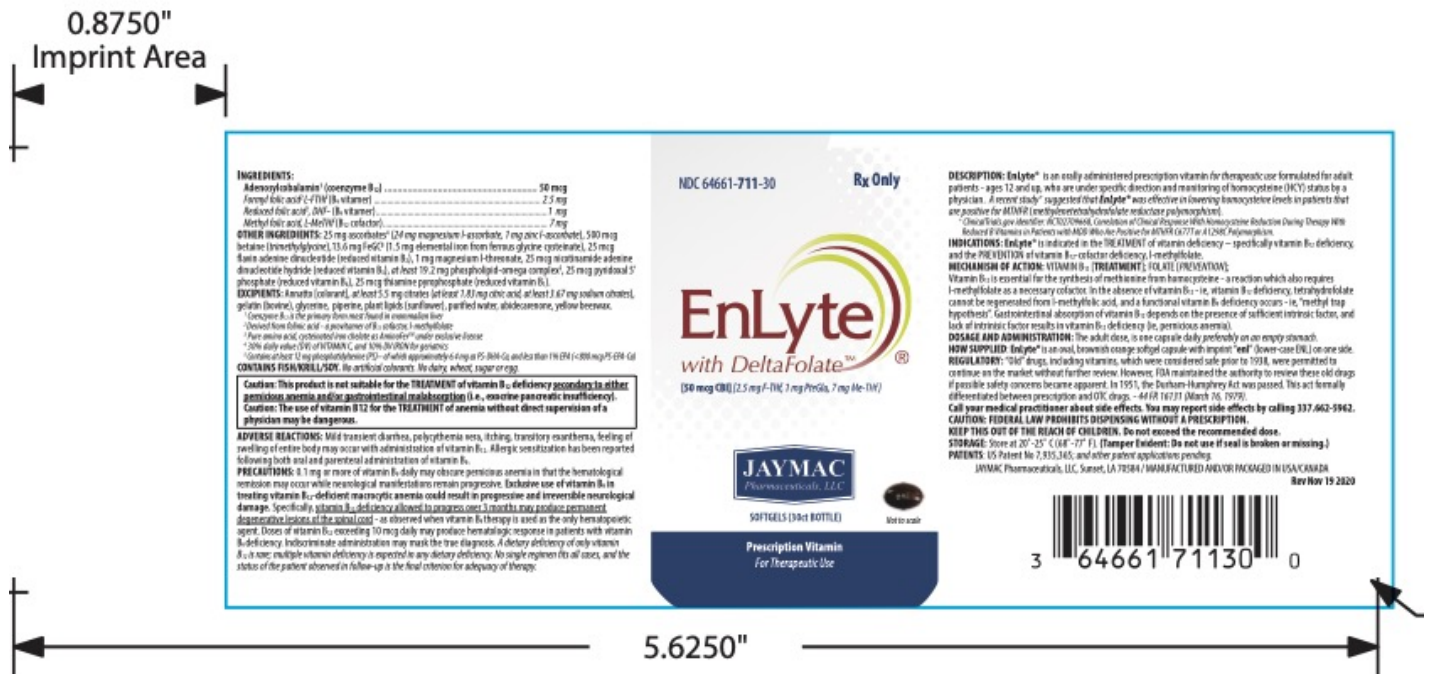
**Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962. KEEP THIS OUT OF THE REACH OF CHILDREN.**

**Do not exceed the recommended dose.**

## HOW SUPPLIED:

Oval, brownish-orange softgel capsule with "ENL"<sup>7</sup> on one side, in bottles of 30 with NDC 64661-711-30.

## Rev Nov 19 2020



leucovorin, folic acid, levomefolate magnesium, ferrous cysteine glycinate, 1,2-docosahexanoyl-sn-glycero-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycero-3-phosphoserine calcium, phosphatidyl serine, pyridoxal 5-phosphate, flavin adenine dinucleotide, nadh, cobamamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium l-threonate and betaine capsule, delayed release pellets

Ingredient Name	Basis of Strength	Strength
<b>LEUCOVORIN</b> (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	2.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

<b>LEVOMEFOLATE MAGNESIUM</b> (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg
<b>FERROUS CYSTEINE GLYCINATE</b> (UNII: 8B4OP7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
<b>1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 6WJM73T46K) (1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:DVY07ILF1W)	1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	6.4 mg
<b>1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 9ABD9DRK7B) (1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:C3019D8IIA)	1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	800 ug
<b>PHOSPHATIDYL SERINE</b> (UNII: 394XK0IH40) (PHOSPHATIDYL SERINE - UNII:394XK0IH40)	PHOSPHATIDYL SERINE	12 mg
<b>PYRIDOXAL PHOSPHATE ANHYDROUS</b> (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
<b>FLAVIN ADENINE DINUCLEOTIDE</b> (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	25 ug
<b>NADH</b> (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug
<b>COBAMAMIDE</b> (UNII: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	COBAMAMIDE	50 ug
<b>COCARBOXYLASE</b> (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
<b>MAGNESIUM ASCORBATE</b> (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	MAGNESIUM ASCORBATE	24 mg
<b>ZINC ASCORBATE</b> (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
<b>MAGNESIUM L-THREONATE</b> (UNII: 1Y26ZZ0OTM) (THREONIC ACID, L- - UNII:75B0PMW2JF)	MAGNESIUM L-THREONATE	1 mg
<b>BETAINE</b> (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 ug
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.83 mg
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	3.67 mg

### Inactive Ingredients

Ingredient Name	Strength
ANNATTO (UNII: 6PQP1V1B6O)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PIPERINE (UNII: U71XL721QK)	
WATER (UNII: 059QF0KO0R)	
UBIDECARENONE (UNII: EJ27X76M46)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

### Product Characteristics

Color	BROWN (annatto)	Score	no score
Shape	OVAL	Size	14mm
Flavor	ORANGE (creamy orange)	Imprint Code	ENL
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64661-711-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/12/2011	

**Labeler** - Jaymac Pharmaceuticals LLC (830767260)

**Registrant** - Jaymac Pharmaceuticals LLC (830767260)

## Establishment

Name	Address	ID/FEI	Business Operations
Viva Pharmaceuticals INC		253288898	manufacture(64661-711)

Revised: 11/2020

Jaymac Pharmaceuticals LLC